Docket No.: B173CIP1

### THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT(S):

Thalia Papayannopoulou

**SERIAL NO.:** 

08/436,339

FILED:

July 13, 1995

FOR:

PERIPHERALIZATION OF HEMATOPOIETIC STEM CELLS

**GROUP ART UNIT:** 

1806

**EXAMINER:** 

Nancy A. Johnson

Assistant Commissioner for Patents Washington, D.C. 20231

#### **RESPONSE**

Sir:

In an Office Action dated October 10, 1996, the Examiner has required restriction to one of the following inventions:

Group I: claims 1-14, drawn to a method of peripheralizing stem cells, classified in Class 424, subclass 144.1.

Group II: claims 15-18, drawn to a method of treating cancer, classified in Class 424, subclass 144.1.

Group III: claims 19-24, drawn to a method of treating AIDS, classified in Class 424, subclass 144.1.

Group IV: claims 25-28, drawn to a gene therapy method, classified in Class 424, subclass 93.1.

The Examiner has alleged that the methods of Groups I-IV differ in the method objectives, the method steps and parameters, and in the reagents used. Further, the Examiner alleges that the inventions are distinct for the "reasons given above" and have acquired a separate status in the art as shown by their different classification and recognized divergent subject matter and because the searches required for the groups are not co-extensive.

Applicants provisionally elect the claims of Group I with traverse. Applicants respectfully submit that restriction in this application is improper because the Examiner has failed to establish that the inventions are independent and distinct, as required by 35 U.S.C. § 121. Specifically, the Examiner has merely stated that the methods, steps; parameters and reagents used are different, without indicating a basis why the claims in Groups I-IV are independent and distinct. Therefore, applicants request that the restriction requirement be withdrawn.

Additionally, the Examiner has indicated that the application contains sequence disclosures which do not comply with the sequence rules. However, this application is the national stage of international application PCT/US93/11060 filed November 15, 1993. The present application entered the national stage under 35 U.S.C. § 371 on May 12, 1995. Upon filing in the U.S. receiving office, applicants submitted a CRF copy of the sequence listing, a paper copy of the sequence listing, and computer readable copies of the same. For the Examiner's convenience, applicants have attached hereto a copy of the PCT transmittal papers indicating that the C.F.R. and appropriate documentation related to the sequence listing were enclosed. Therefore, applicants do not believe that resubmission of the CRF copy of the sequence listing and related documentation is required. If these documents have been misplaced or separated from the Examiner's files, kindly contact the undersigned and duplicates will be provided.

Applicants respectfully request prompt and favorable action on the merits of this application.

Respectfully submitted,

erry A. Flynn

Attorney for Applicant(s)

Reg. No. 33,693

Biogen, Inc.

14 Cambridge Center Cambridge, MA 02142

\*EXPRESS MAIL\* mailing label number EM046583385US

Date of Deposit October 23, 1996

I hereby certify that this paper/fee is being
deposited with the United States Postal Service "EXPRESS
MAIL POST OFFICE TO ADDRESSEE" service under 37 C.F.R. 1.10
on the date indicated above and is addressed to the Hon.
Assistant Commissioner to: Patents, Washington, D.C. 20231

Jaula T. Xurst

Attorney Docket No. B173 CIP PCT

## IN THE UNITED STATES RECEIVING OFFICE OF THE PATENT COOPERATION TREATY

Applicants

Board of Regents of University of

Washington et al.

For

PERIPHERALIZATION OF HEMATOPOIETIC

STEM CELLS

Filed

: Concurrently herewith

15 November 1993

New York, New York 15 November 1993

Hon. Commissioner of Patents and Trademarks Washington, D.C. 20231 Attention: RO/US

STATEMENT TO VERIFY CONTENT OF COMPUTER READABLE FORM SUBMISSION UNDER 37. C.F.R. § 1.821(f)
Sir:

I hereby state that the content of the paper and the computer readable copy of the Sequence Listing, submitted in the above-identified international application in accordance with 37 C.F.R. § 1.821(c) and (e), respectively, are the same.

Respectfully submitted,

Immac J. Thampoe (Reg. No. 36,322)

Patent Agent for Applicants

c/o FISH AND NEAVE

1251 Avenue of the Americas New York, New York 10020

Tel.: (212) 596-9000

# **PCT**

## **REQUEST**

For receiving Office use only	-
International Application No.	
International Filing Date	-
Name of receiving Office and "PCT International Application"	

The undersigned requests that the present international application be processed according to the Patent Cooperation Treaty.	Name of receiving Office and "PCT International Application"				
	Applicant's or agent's file reference (if desired)(12 characters maximum) B173 CIP PCT				
Box No. I TITLE OF INVENTION					
PERIPHERALIZATION OF HEMA	ATOPOIETIC STEM CELLS				
Box No. II APPLICANT					
Name and address: (Family name followed by given name: for a designation. The address must include postal companies.)  BOARD OF REGENTS OF UNIVERSITY	legal entity, full official ode and name of country.)  This person is also inventor.				
OF WASHINGTON Office of Technology Transfer	Telephone No. (206) 543-3970				
4225 Roosevelt Way, N.E., Suite Seattle, Washington 98105 United States of America	Facsimile No. (206) 685-4767				
	Teleprinter No.				
State (i.e. country) of nationality:	State (i.e. country) of residence:				
United States of America This person is applicant all designated a	United States of America				
	States except the United States the States indicated in the Supplemental Box				
Box No. III FURTHER APPLICANTS AND/OR (FURTHI	ER) INVENTORS				
Name and address: (Family name followed by given name: for a designation. The address must include postal co	n legal entity, full official ode and name of country.)  This person is:				
PAPAYANNOPOULOU, Thalia	applicant only				
3336 Cascadia Avenue South Seattle, Washington 98144					
United States of America	X applicant and inventor				
	inventor only (If this check-box is marked, do not fill in below.)				
State (i.e. country) of nationality:	State (i.e. country) of residence:				
United States of America	United States of America				
This person is applicant all designated for the purposes of:	States except				
Name and address: (Family name followed by given name: for a legal entity, full official designation. The address must include postal code and name of country.)  This person is:					
	applicant only				
	applicant and inventor				
	inventor only (If this check-box is marked, do not fill in below.)				
State (i.e. country) of nationality:	State (i.e. country) of residence:				
This person is applicant all designated for the purposes of:					
Further applicants and/or (further) inventors are indicated on	a continuation sheet.				

Sheet	No.	4								ı	١	
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Box No. IV AGENT OR COMMON REPRESENTATE	IVE. OR ADDRESS FOR GORDESPONDENCE
The person identified below is hereby/has been appointed to	IVE: OR ADDRESS FOR CORRESPONDENCE
Author	inties as: A agent Common representati
Name and address: (Family name followed by given name: designation. The address must include post	tal code and name of country.)
HALEY, James F. Jr.	(212) 596-9000
THAMPOE, Immac J.	Fascimile No.
c/o Fish & Neave 1251 Avenue of the Americas	(212) 596-9090
New York, New York 10020	<b>飛鈴松崎</b> Telex No.
United States of America	1
Mark this check-box where no agent or common seem	esentative is/has been appointed and the space above is used instead the space above is used instead to the space above in the space above is used instead to the space above its used instead to the space above its used instead to the space above its used in the
punctified an	hould be sent.
DESIGNATION OF STATES	
The following designations are hereby made under Rule 4.9(a Regional Patent	a) (mark the applicable check-boxes; at least one must be marked):
EL European Patent: AT Austria, BE Belgium, CH	f and LI Switzerland and Liechtenstein, DE Germany, DK Denmark
Convention and of the PCT	any other State which is a Contracting State of the European Paten
Mali, Mauritania Niger Separat Torre	Central African Republic, Chad, Congo, Côte d'Ivoire, Gabon, Guinea
Vational Patent (if other had of passession and	sired, specify on dotted line)
National Patent (if other kind of protection or treatment desired, spe	ecify on dotted line):
AT Austria	MN Mongolia
AU Australia	MW Malawi
BB Barbados	NL Netherlands
BG Bulgaria	
	NO Norway
BR Brazil	X NZ New Zealand
	PL Poland
CA Canada	PT Portugal
CH and LI Switzerland and Liechtenstein	RO Romania
CZ Czech Republic	RU Russian Federation
DE Germany	SD Sudan
DK Denmark	<b>=</b>
	SE Sweden
	SK Slovakia
	UA Ukraine
GB United Kingdom	US United States of America
HU Hungary	Continuation-in-Part
JP Japan	☐ VN Viet Nam
KP Democratic People's Republic of Kores	
	Check haves meaned for during the grant of the grant
KR Republic of Korea	Check-boxes reserved for designating States (for the purposes of a national patent) which have become party to the PCT after
1000 000 000	issuance of this sheet:
KZ Kazakhstan	<b></b>
LK Sri Lanka	
LU Luxembourg	
MG Madagascar	<u> </u>
	<b>-</b>
addition to the designations made above the anti-	
der the PCT except the designation(s) of	makes under Rule 4.9(b) all designations which would be permitted
applicant declares that those additional designations are sub-	ect to confirmation and that any designation which is not confirmed
it. (Confirmation of a designation the priority date is to be re	ext to confirmation and that any designation which is not confirmed regarded as withdrawn by the applicant at the expiration of that time cifying that designation and the payment of the designation and confirmation line line.
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Use this box in the following cases:

1. If, in any of the Boxes, the space is insufficient to furnish all the information:

in particular:

- (i) if more than three persons are involved as applicants and/or inventors and no "continuation sheet" is available:
- (ii) if, in Box No. II or in any of the sub-boxes of Box No. III. the indication "the States indicated in the Supplemental Box" is checked:
- (iii) if, in Box No. II or in any of the sub-boxes of Box No. III, the inventor or the inventor/applicant is not inventor for the purposes of all designated States or for the purposes of the United States of America:
- (iv) if, in addition to the agent(s) indicated in Box No. IV, there are further agents:
- (v) if. in Box No. V, the name of any State (or OAPI) is accompanied by the indication "patent of addition," "certificate of addition," or "inventor's certificate of addition," or if, in Box No. V, the name of the United States of America is accompanied by an indication "Continuation" or "Continuation-inpart":
- (vi) if there are more than three earlier applications whose priority is claimed:
- 2. If the applicant claims, in respect of any designated Office, the benefits of provisions of the national law concerning non-prejudicial disclosures or exceptions to lack of novelry:

in such case, write "Continuation of Box No. ..." [indicate the number of the Box] and furnish the information in the same manner as required according to the captions of the Box in which the space was insufficient;

in such case, write "Continuation of Box No. III" and indicate for each additional person the same type of information as required in Box No. III;

in such case, write "Continuation of Box No. II" or "Continuation of Box No. III" or "Continuation of Boxes No. II and No. III" (as the case may be), indicate the name of the applicant(s) involved and, next to (each) such name, the State or States (and/or, where applicable, European or OAPI patent) for the purposes of which the named person is applicant:

in such case, write "Continuation of Box No. II" or "Continuation of Box No. III" or "Continuation of Boxes No. II and No. III" (as the case may be), indicate the name of the inventor(s) and, next to (each) such name, the State or States (and/or, where applicable, European or OAPI patent) for the purposes of which the named person is inventor;

in such case, write "Continuation of Box No. IV" and indicate for each further agent the same type of information as required in Box No. IV;

in such case, write "Continuation of Box No. V" and the name of each State involved (or OAPI), and after the name of each such State (or OAPI), the number of the parent title or parent application and the date of grant of the parent title or filing of the parent application:

in such case, write "Continuation of Box No. VI" and indicate for each additional earlier application the same type of information as required in Box No. VI.

in such case, write "Statement Concerning Non-Prejudicial Disclosures or Exceptions to Lack of Novelty" and furnish that statement below.

### Continuation of Box No. V

United States of America application no. 07/977,702 filed 13 November 1992 (13.11.92)

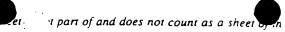
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Box No. VI PRIORITY	_AIM	Further priority o	laims are indicated in	in the Supplemental Box
The priority of the following	earlier application(s) is he	ereby claimed:	ianns are moreated i	iii tile Supplemental Box
Country (in which, or for which, the application was filed)	Filing Date (day/month/year)	Aŗ	oplication No.	Office of filing tonly for regional or international application
US	13 November (13.11.92)	1992 07/9	77,702	- apprenie
lem (2)	4			
item (3)				
Box No. VII EARLIER SE	nereby requested to prepare of the earlier application(s	e and transmit to the In identified above as ite	em(s): (1)	
Fill in where a search (international, Authority is now requested to base the reference to the relevant application (Country (or regional Office):	international-type or other) by international search, to the ext or the translation thereof) or by Date (day/m	v reference to the search requ	Authority has already b that earlier search. Ide uest: Number:	een carried out or requested and the nify such search or request either b
Box No. VIII CHECK LIST				
This international application the following number of shee 1. request : 4 2. description : 43 3. claims : 5 4. abstract : 1 5. drawings : 10  Total : 63	sheets	emational application is separate signed power of attorney copy of general power of attorney statement explaining lack of signature priority document(s) identified in Box No. V as item(s):	5. X fee c. 6. separ depos 7. X nucle seque 7. 8. X other	alculation sheet  rate indications concerning sited microorganisms  otide and/or amino acid nce listing (diskette)  (specify): cheque;
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International Searching Author specified by the applicant:	ty ISA/	6. Transmittal until search	of search copy del	ayed

For International Bureau use only Date of receipt of the record copy by the International Bureau:



PCT INTERNATIONAL APPLICATION TRANSMI	TTAL LETTER	15 November 1993 (15.11
REGARDING THE INTERNATIONAL APPLICATION OF BOARD UNIVERSITY OF WASHINGTON et a		DOCKET OR REFERENCE NUMBER B173 CIP PCT
NTITLED PERIPHERALIZATION OF HEMATOPO	IETIC STEM CELL	S
Certification under	37 CFR 1.10 (if appli	cable) 15 November 1993
HB309709224 US		(15.11.93)
"Express Mail" mailing number		Date of Deposit
hereby certify that this application is being deposited Addressee" service under 37 CFR 1.10 on the date increasements. Washington, D.C. 20231.	with the United States Pos- iicated above and is address	tal Service "Express Mail Post Office to ed to the Commissioner of Patents and
(Typed or printed name of person mailing application)		(Signature of person mailing application)
To the United States Receiving Office (RO/US):		
Accompanying this transmittal letter is the aborequest form (PCT/RO/101). Please process the ation Treaty.	ve-identified International application according to	Il application, including a completed the provisions of the Patent Cooper-
The following requests are made of the RO/US:		
1. X PREPARATION AND TRANSMITTAL prepare and transmit to the International documents identified in Box VI of the Req	al Bureau a certified copy	F PRIORITY DOCUMENTS—Please of the United States origin priority
To cover the cost of copy preparation and a (check) ensurement of including \$12.0 the RO/US is hereby authorized to cha	certification (37 CFR 1.190) at of \$ 3352.00 10 for certified rge the following deposit acc	a)(3) and (b)(1)). is attached to this transmittal letter. i CODY) ount no
The appropriate Search fee for the abor (PCT/RO/101 Annex).		
2. SUPPLEMENTAL SEARCH FEES (O SEARCH.)—Please charge any Supplem International Searching Authority (ISA/U	nental Search fees that m	ONDUCTS THE INTERNATIONAL nay be required by the United States
I understand that this authorization is subject to my to submit a protest against payment of the Supplem may timely complete the Search Report.	v oral confirmation thereof in each ental Search fees, but is merely an	instance and that it in no way limits my right administrative aid to assure that the ISA/US
NOTE: SUPPLEMENTAL SEARCH FEES FO PATENT OFFICE		
3. X DISCLOSURE INFORMATION—in or cation for purposes of determining wheth the following information is supplied:	der to assist in screening her a license for foreign tr	the accompanying International appli- ransmittal should and could be granted,
A. There is no prior filed application	relating to this invention.	13 November 19
B. 🗵 There is a prior application*, so which contains subject matter t	erial number <u>07/977,</u> that is	702 filed on (13.11.92)
1. substantially identical to $2.$ less than that of the $a$	accompanying Internation	al application. The additional subject
matter of the Internation $3.$ $\square$ more than that of the ac	al application appears on pa companying International	ges(s) and line(s) THROUGHOUT application.
C. Disclosure information cannot be involvement of several prior which the disclosure information	applications or for oth	e of Points 4A or 4B above due to the er reasons. A separate sheet on this transmittal letter.
4. X REQUEST FOR FOREIGN TRANSN 184 and 37 CFR 5.11, a license to trans or international authorities is hereby requ	mit the accompanying Inte	ording to the provisions of 35 U.S.C. emational application to foreign agencies
* Priority is not claimed, unless all necessary into	rmation is listed in Box VI of	the Request Form (PCT/RO/101).
SIGNER 13 THE	AME OF SIGNER LIVERS	c
APPLICANT	Immac J. Thampo	
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REG NO 36,322	THE am	-pre

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ICI	For receiving Office use only
FEE CALCULATION SHEET	
Annex to the Request	International application No.
Applicant's or agent's B173 CIP PCT	Date stamp of the receiving Office
Applicant	
BOARD OF REGENTS OF UNIVERSITY OF WA	SHINGTON et al.
CALCULATION OF PRESCRIBED FEES	
1. TRANSMITTAL FEE	200. T
2. SEARCH FEE	1512. S
International search to be carried out by EPO	1512. [3]
(If two or more International Searching Authorities are competent in relation application, indicate the name of the Authority which is chosen to carry out the	on to the international
	international search.)
3. INTERNATIONAL FEE	
Basic Fee The international application contains 63 sheets.	
first 30 sheets	
$\frac{33}{\text{remaining sheets}} \times \frac{10.}{\text{additional amount}} = 33$	0.  b,
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Designation Fee	
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(If that total exceeds the figure which corresponds to the amount of the	∦.
designation fee multiplied by ten, enter the latter figure in box D.)	<u> </u>
Add amounts entered at B and D and enter total at I	1628.
4. FEE FOR PRIORITY DOCUMENT	
5. TOTAL FEES PAYABLE	12. P
Add amounts entered at T. S. Land P.	
and enter total in the TOTAL box	3352.
	TOTAL
The designation fee is not paid at this time.	
MODE OF PAYMENT	
authorization to charge bank draft	
deposit account (see below)	coupons
	other (specify):
postar money order revenue stamps	
DEPOSIT ACCOUNT AUTHORIZATION (this mode of payment may no	ot be available at all receiving Offices)
The RO/ US is hereby authorized to charge the total fees in	
is hereby authorized to charge any deficiency deposit account.	or credit any overpayment in the total fees indicated above to my
is hereby authorized to charge the fee for preparation by Bureau of WIPO to my deposit account.	aration and transmittal of the priority document to the International
15 November 1993	
(13.11.73)	H Jagra
Deposit Account Number Date (day/month/year)	Signature Immac J. Thampoe